

*Amendment and Response Under 37 C.F.R. §1.116 - Expedited Examining Procedure*

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Serial No.: 09/738,599

Confirmation No.: 1240

Filed: December 15, 2000

For: NUCLEIC ACID ENCODING AN AVIAN E.COLI ISS POLYPEPTIDE AND METHODS OF USE**Remarks**

The Office Action mailed April 18, 2003 has been received and reviewed. Claims 35, 37, 38, 41, 42, 46, 48, 57-59, 61, 63, and 67 having been amended, and claims 68-70 having been added, the pending claims are claims 30-33 and 35-70. Claims 35, 36, and 46-66 have been withdrawn from examination by the Examiner, such that claims 30-33, 37-45, and 67 are presently under examination. Reconsideration and withdrawal of the rejections are respectfully requested

In the "Remarks" section of the Office Action mailed April 18, 2003 (page 6, paragraph 25), the Examiner asserted that claim 38 was confusing in the recitation of "the nucleic acid molecule comprises a vector." While the claim was not rejected or objected to, in order to facilitate prosecution of the present application, claim 38 is amended substantially as suggested by the Examiner to recite "the nucleic acid molecule is included in a vector."

Claim 35 is amended to correct a typographical error.

Support for the amendment of claim 37 to recite "isolated" can be found throughout the specification. Support for the other amendment of claim 37 is claim 41 as originally filed.

The amendment of claim 41 is supported by the specification at, for instance, page 48, lines 5-17.

New claim 68 is supported by claims 37 and 41 as originally filed, and by the specification at, for instance, page 8, lines 6-7, and page 49, lines 3-17.

New claim 69 is supported by claims 37 and 44 as originally filed, and by the specification at, for instance, page 8, lines 6-7, and page 49, lines 3-17.

New claim 70 is supported by claims 37, 43, and 45 as originally filed, and by the specification at, for instance, page 8, lines 6-7, and page 49, lines 3-17.

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**Double Patenting Rejection**

Claims 30-33 were rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 17 of U.S. Patent No. 6,087,128, and claims 37-44 and 67 were rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-5 of U.S. Patent No. 6,087,128. These rejections are respectfully traversed. In the interest of furthering prosecution, submitted herewith is a Terminal Disclaimer which, Applicants submit, is in compliance with 37 CFR 1.321(c) and thereby obviates the Examiner's double patenting rejection of pending claims 30-33, 37-44, and 67.

Reconsideration and withdrawal of this rejection of claims 30-33, 37-44, and 67 is respectfully requested.

**The 35 U.S.C. §112, Second Paragraph, Rejection**

The Examiner maintained the rejection of claim 42 under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. This rejection is respectfully traversed.

Claim 42 is amended to recite an "immunostimulatory nucleotide sequence." Applicants apologize for not including this amendment in the Response mailed January 30, 2003. The Examiner is requested to note the statements made regarding this rejection at page 18 of the Response mailed January 30, 2003. Reconsideration and withdrawal of this rejection is respectfully requested.

Newly added claim 67 was rejected under 35 U.S.C. §112, second paragraph, as being indefinite in the recitation "wherein the immunogenic composition generates an antibody response when administered to a subject," because it is unclear to what the antibody response is generated to: nucleic acid, its subunit or its fragment, or the product encoded by the nucleic acid molecule, its subunit or its fragment. This rejection is respectfully traversed. However, in the interests of furthering prosecution, claim 67 is amended to recite "wherein the immunogenic

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composition generates an antibody response against the polypeptide, subunit, or fragment when administered to a subject." It is believed that this amendment obviates the rejection.

Reconsideration and withdrawal of the rejection of claims 42 and 67 under 35 U.S.C. §112, second paragraph, is respectfully requested.

**The 35 U.S.C. §102 Rejection**

The Examiner rejected claims 37-40, 43, and 67 under 35 U.S.C. §102(b) as being anticipated by Barondess et al., "A Bacterial Virulence Determinant Encoded by Lysogenic Coliphage  $\lambda$ ," *Nature*, 346(6287):871-874 (1990) or Chuba et al., "Cloning and DNA Sequence of Plasmid Determinant *iss*, coding for increased serum survival and surface exclusion, which has homology with lambda DNA," *Mol. Gen. Genet.*, 216(2-3):287-292 (1989) as evidenced by Harlow et al., in *Antibodies: A laboratory Manual*, Cold Spring Harbor Laboratory, Chapter 5, page 76 (1988). This rejection is respectfully traversed. In the interests of furthering prosecution, claim 37 is amended to recite the subject matter of claim 41. It is believed that this amendment obviates the rejection.

Reconsideration and withdrawal of the rejection of claims 37-40, 43, and 67 under 35 U.S.C. §102(b) is respectfully requested.

**Request for Rejoinder under 37 CFR §1.121**

Claims 35, 36, and 46-66, directed to a process for making and using a product, were previously withdrawn from examination pursuant an election filed in response to the Restriction Requirement mailed June 25, 2002. Claims 35, 36, and 46-66 are amended herewith to include all the limitations of the examined product claims. Pursuant to the procedures set forth in the Official Gazette notice dated March 26, 1996 (1184 O.G. 86), withdrawal of the restriction requirement as it relates to claims 35, 36, and 46-66, and rejoinder and examination of previously withdrawn claims 35, 36, and 46-66, as amended herein, is respectfully requested.

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It is respectfully submitted that the pending claims 30-33 and 35-70 are in condition for allowance and notification to that effect is respectfully requested. The Examiner is invited to contact Applicants' Representatives, at the below-listed telephone number, if it is believed that prosecution of this application may be assisted thereby.

Respectfully submitted for  
Nolan et al.

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Sept. 17, 2003  
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**CERTIFICATE UNDER 37 CFR §1.8:**

The undersigned hereby certifies that this paper is being transmitted by facsimile in accordance with 37 CFR §1.6(d) to the Patent and Trademark Office, addressed to Assistant Commissioner for Patents, Mail Stop AF, P.O. Box 1450, Alexandria, VA 22313-1450, on this 17 day of SEPTEMBER, 2003, at 2:47 pm (Central Time).

By: SAM HER  
Name: SAM HER